K080434

510(k) Summary of Safety and Effectiveness
InterTAN™ CHS Plating System
**Plates, Lag Screws, Compression Screws and Accessories**

APR 10 2008

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| **Submitted By:** | Smith & Nephew, Inc., Orthopaedic Division<br>1450 Brooks Road<br>Memphis, TN 38116 |
| **Date:** | February 15, 2008 |
| **Contact Person:** | Elizabeth Miller, Regulatory Affairs Project Manager<br>Tel: (901) 399-6176 Fax: (901) 399-1557 |
| **Proprietary Name:** | **InterTAN™ CHS Plating System -**<br>***Plates, Lag Screws, Compression Screws and Accessories*** |
| **Common Name:** | Bone Plates and Bone Screws |
| **Classification Name and Reference:** | 21 CFR 888.3030, single/multiple component metallic bone fixation appliances and accessories - Class II<br>21 CFR 888.3040, smooth or threaded metallic bone fixation fastener - Class II |
| **Device Product Code and Panel Code:** | KTT, HWC / Orthopedics / 87 |

**Device Description:**
The design of the **InterTAN™ CHS Plating System** is based on design features of the following currently marketed products: PERI-LOC™ Periarticular Locked Plating System, TriGen InterTAN Nail and CHS. InterTAN™ CHS System is designed to address fractures of the proximal femur. System components include bone plates, lag screws, compression screws, and associated accessories. Like the predicate devices listed below, the subject components include various hole configurations and barrel angles of the contoured locking bone plates and various lengths of the lag/compression screws made from stainless steel and titanium. Further InterTAN™ CHS femoral locking bone plates, incorporate a screw-to-plate locking feature along the shaft of the plate which forms a locked, fixed angle construct to aid in holding fracture reduction.

**Intended Use:**
InterTAN™ CHS Proximal Femur Locking Bone Plates and Bone Screws are indicated for:
1.) Intracapsular fractures of the proximal femur (For certain high subcapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head).
2.) Intertrochanteric fractures.
3.) Stable and unstable fractures of the proximal femur in which medial cortex stability can be restored.
4.) Hip osteotomy

Components in the InterTAN™ CHS Plating System are for single use only.

**Technological Characteristics:**
Components comprising the **InterTAN™ CHS Plating System** are similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials, and incorporate similar technological characteristics.

**Substantial Equivalence Information:**
When compared to the predicate devices listed below, substantial equivalence is based on similarities in design features, overall indications for use, and material composition.

- PERI-LOC™ Periarticular Locked Plating System Proximal Femur Bone Plates and Bone Screws – K072818
- PERI-LOC™ Periarticular Locked Plating System – K033669
- TriGen InterTAN Nail- K040212
- Smith & Nephew Compression Hip Screw- K993289
- Orthofix Gotfried Pc.C.P.- K983814
- DePuy Ace Captured Hip Screw- K813554

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Ms. Elizabeth Miller
Project Manager, Regulatory Affairs
1450 Brooks Rd.
Memphis, TN 38116

APR 10 2008

Re: K080434
Trade/Device Name: InterTAN™ CHS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDO, KTT
Dated: February 15, 2008
Received: February 19, 2008

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): K080434

Device Name: InterTAN™ CHS Plating System –

Indications for Use:

InterTAN™ CHS Proximal Femur Locking Bone Plates and Bone Screws are indicated for:

1.) Intracapsular fractures of the proximal femur

2.) Intertrochanteric fractures.

3.) Stable and unstable fractures of the proximal femur in which medial cortex stability can be restored.

4.) Hip osteotomy

* For certain high intracapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head.

Components in the InterTAN™ CHS Plating System are for single use only.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080434